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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,956	04/06/2006	Steven J. Norris	UTSH:264US/10506328	9208

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
03/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,956	NORRIS, STEVEN J.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. THE PRIOR RESTRICTION REQUIREMENT MAILED 23 JUNE 2008 IS HEREBY VACATED.

New Matter

2. The amendments filed 2 March 2009 and 16 December 2009 are objected to under 35 U.S.C. 132(a) because they introduce new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The originally filed sequence listing was received on 17 June 2005.

The sequence listing filed 2 March 2009 changed the sequences beginning with SEQ ID NO:5. Originally presented SEQ ID NO:5 and NO:6 were completely removed from the listing. Thus, the sequences with SEQ ID NOs: 5-116 are not the sequences originally filed under the designations of SEQ ID NO:5-116.

The sequence listing filed 16 December again changed the sequences the sequences with SEQ ID NOs: 5-116 are not the sequences originally filed under the designations of SEQ ID NO:5-116.

Applicant is required to cancel the new matter in the reply to this Office Action.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 2-16, drawn to nucleic acid encoding SEQ ID NO:6, classified in class 536, subclass 23.7.

II. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:8, classified in class 536, subclass 23.7.

III. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:10, classified in class 536, subclass 23.7.

IV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:12, classified in class 536, subclass 23.7.

V. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:14, classified in class 536, subclass 23.7.

VI. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:16, classified in class 536, subclass 23.7.

VII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:18, classified in class 536, subclass 23.7.

VIII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:20, classified in class 536, subclass 23.7.

IX. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:30, classified in class 536, subclass 23.7.

X. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:32, classified in class 536, subclass 23.7.

XI. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:34, classified in class 536, subclass 23.7.

XII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:36, classified in class 536, subclass 23.7.

XIII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:38, classified in class 536, subclass 23.7.

XIV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:40, classified in class 536, subclass 23.7.

XV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:52, classified in class 536, subclass 23.7.

XVI. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:54, classified in class 536, subclass 23.7.

XVII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:56, classified in class 536, subclass 23.7.

XVIII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:59, classified in class 536, subclass 23.7.

XIX. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:61, classified in class 536, subclass 23.7.

XX. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:63, classified in class 536, subclass 23.7.

XXI. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:65, classified in class 536, subclass 23.7.

XXII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:67, classified in class 536, subclass 23.7.

XXIII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:69, classified in class 536, subclass 23.7.

XXIV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:71, classified in class 536, subclass 23.7.

XXV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:73, classified in class 536, subclass 23.7.

XXVI. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:77, classified in class 536, subclass 23.7.

XXVII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:79, classified in class 536, subclass 23.7.

XXVIII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:81, classified in class 536, subclass 23.7.

XXIX. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:83, classified in class 536, subclass 23.7.

XXX. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:85, classified in class 536, subclass 23.7.

XXXI. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:87, classified in class 536, subclass 23.7.

XXXII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:91, classified in class 536, subclass 23.7.

XXXIII. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:93, classified in class 536, subclass 23.7.

XXXIV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:95, classified in class 536, subclass 23.7.

XXXV. Claim 2-16, drawn to nucleic acid encoding SEQ ID NO:97, classified in class 536, subclass 23.7.

4. The inventions listed as Groups I-XXXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each group is drawn to a structurally nonidentical nucleic acid sequence which constitutes a different special technical feature.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. The search for Groups I--XXXV would each require the search of the extensive sequence database followed by the analysis of the enormous results that accumulate after the search. This would impose a serious burden on the Examiner. Advances over the past five-ten years in automated sequencing, polynucleotide/polypeptide characterization techniques have made such activities routine. The entire genome of several organisms, including humans, has been determined and deposited into nucleotide and polypeptide sequence databases. The advances in nucleic acid and polypeptide sequencing techniques have also lead to the exponential growth

in the size of nucleic acid and polypeptide sequence databases and an increase in the number and complexity of such databases. For example the GenBank® database in 1996 contained 1,021,211 nucleotide sequences. In 2000 the database contained 10,106,023 nucleotide sequences, about a seventeen-fold increase in the number of nucleotides and about a tenfold increase in the number of sequences. In February 2006, the GenBank database contained 59,750,386,305 bases in 54,584,635 sequence records or about a ninety-one-fold increase in the number of nucleotides and about a fifty-four-fold increase in the number of sequences. These factors are responsible for exacerbating the search and examination burden faced by the Office with respect to polynucleotide or polypeptide inventions claimed and described in currently filed applications. It now requires significantly more computational time to run individual nucleotide or polypeptide sequence searches for examination purposes than in 1996, and there is significantly more sequence search results and pertinent prior art to consider. In addition, it currently takes more Office resources to correlate the claimed polynucleotide/polypeptide with the polynucleotide/polypeptide as defined in the prior art because it is increasingly common for both patent applicants and prior art references to describe a polynucleotide/polypeptide molecule in different ways.

Restriction Requirement Applicable to all Groups

8. Furthermore, the presence of multiple polypeptide sequences and polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of

hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Rejoinder of all or a specified subset of the sequences is possible if Applicants provide a single and specific representative subsequence found in all or a specified subset of the sequences for search, and state that all or a specified subset of the sequences are not patentably distinct. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement of a patentably distinct product, not an election of species.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper

restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 1, 2010